

## **II. REMARKS**

### **A. Status of the Claims**

Claims 2-19 were pending in the case at the time the Action was mailed. Claim 9 has been amended, as described below. Thus, claims 2-19 remain pending.

### **B. The Enablement Rejection Is Overcome**

Claims 2-7 and 9-19 are rejected under 35 U.S.C. § 112, first paragraph, as failing the enablement requirement. In particular, the Action asserts that the specification does not reasonably provide enablement for thiazolidinedione compounds other than troglitazone, pioglitazone and BRL49653. Action, page 3. Applicant respectfully disagrees.

The Examiner cites *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), in an attempt to support the enablement rejection. However, in *Wands*, the Federal Circuit found sufficient enabling support for the claims at issue and overturned the Office's enablement rejection.

The Examiner's enablement rejection appears to focus namely on Applicant's claimed thiazolidinedione genus. Action at page 4. The following portion from the *Manual of Patent Examination Procedure* (MPEP) is relevant in this regard:

For a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation.

MPEP § 2164.02. This passage provides the framework for addressing the enablement rejection, in that (1) representative examples are supplied in the specification in accordance with 35 U.S.C. § 112, first paragraph, and (2) the specification further supplies proof of enablement regarding how to identify, make and use thiazolidinediones in the context of the claimed invention.

**1. The Specification Provides Sufficient Representative Examples to Enable the Claimed Genus of Thiazolidinediones**

The MPEP passage above reflects long-standing patent law that the recitation of representative examples in the specification is sufficient to meet the enablement requirement. *See, e.g., In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) (explaining that as long as the specification discloses at least one method of making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement is satisfied). The present specification sets forth such representative examples: thus, the enablement rejection is unwarranted in this regard.

For example, the specification recites at least three specific thiazolidinediones that may be employed in the claimed methods: troglitazone, pioglitazone and BRL49653. *See, e.g.*, page 5, lines 5-8, and original claims 8 and 9. Indeed, the Action concedes that each of these three thiazolidinediones is enabled by the specification. Action, page 3. Further, contrary to the Action's assertion that only one thiazolidinedione is recited in the working examples (Action, page 6), each of these three thiazolidinediones was studied in Example 2 at page 29, lines 15-24 of the specification (describing nanomolar and micromolar IC<sub>50</sub> measurements of these agents in an oxytocin receptor binding assay). Such recitation of representative examples is all that the law requires to meet the enablement requirement. That is, these examples provide sufficient guidance to a skilled artisan to practice the claimed invention without undue experimentation. For this reason alone, the enablement rejection should be withdrawn.

**2. The Specification Provides a Sufficient Number of Thiazolidinediones to Enable the Claimed Genus**

The Action repeatedly asserts that the specification fails to provide sufficient guidance to a skilled artisan regarding how to select thiazolidinediones that may be employed in the claimed invention. *See, e.g.*, Action, pages 4-8. For example, the Action contends that the specification

“fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation” (Action, page 5) and that “the claims read on all compounds possessing the envisioned physiological activity, disclosed, or undisclosed, regardless [of] the structural formula of these compounds.” Action, page 4. Applicant respectfully disagrees.

The thiazolidinediones of the pending claims are fully enabled by the specification. It is well-settled patent law that “the first paragraph of § 112 requires nothing more than objective enablement.” *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971). This objective enablement may be provided through broad terminology or illustrative examples. *Id.* Moreover, the specification, in combination with the knowledge of a skilled artisan, may together satisfy the enablement requirement. MPEP § 2164.01 (“The test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” (citing *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988))). Such examples and enabling descriptions, read in view of the knowledge of a person of skill in the art, are provided in the specification in satisfaction of the enablement requirement, as described below.

**a. The Specification Discloses Sufficient Illustrative Examples of Thiazolidinediones and Methods of Obtaining and Making Them**

As discussed above, the Action admits that the specification is enabling for three exemplary thiazolidinedione compounds: troglitazone, pioglitazone and BRL49653. Action, page 3. These are the only thiazolidinediones discussed by the Action, and the Action asserts that “the application is silent with regard to selection of any additional compounds” that might function in the same way as these compounds. *Id.*, page 5. However, many additional thiazolidinediones are recited in the specification that may be employed in the present claims. For example, at page 8, lines 12-14, U.S. Patents 5,478,852 and 5,814,647 are noted as reciting “exemplary thiazolidinediones” that may be employed by the present invention. Each of these

patents is incorporated into the specification by reference<sup>\*</sup>, and each recites multiple examples of thiazolidinediones.

Moreover, beginning at page 14, line 25, the following documents are cited as containing thiazolidinedione and thiazolidinedione-like compounds, as well as methods of obtaining and making them: U.S. Patents 5,968,960; 5,223,522; 5,132,317; 5,120,754; 5,061,717; 4,897,405; 4,873,255; 4,687,777; 4,572,912; 4,287,200; 5,002,953; 5,972,944; 5,965,589; 5,910,592; 5,811,439; 5,506,245; 4,340,605; 4,438,141; 4,461,902; 4,703,052; 4,725,610; 4,897,393; 4,918,091; 4,948,900; 5,194,443; 5,232,925; and 5,260,445; WO 91/07107; WO 92/02520; WO 94/01433; WO 89/08651; and JP Kokai 69383/92. Each of these documents was also incorporated by reference into the specification. *Id.* Taken together with troglitazone, pioglitazone and BRL49653, the thiazolidinediones recited in these documents provide numerous examples of this genus of compounds and methods of obtaining and making them. A skilled artisan would not be required to engage in undue experimentation in order to ascertain thiazolidinediones that may be employed in the present invention in view of these illustrative examples.

**b. A Thiazolidinedione Moiety Is Present In Each Thiazolidinedione of the Claimed Genus**

As the *Marzocchi* court held, enablement may be met by the recitation of broad terminology in the specification. 439 F.2d at 223. This holding aligns with other standards of patent law concerning claim breadth, such as that set forth in MPEP § 2164.08, which states,

As concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled

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<sup>\*</sup> "Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. *The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed.*" MPEP § 2163.07(b) (emphasis added). Thus, for any document cited in the specification that is incorporated by reference, the information therein is to be considered part of the specification.

in the art by the disclosure is commensurate with the scope of protection sought by the claims.

While the Action contends that the genus of claimed thiazolidinediones is improperly broad and that a skilled artisan would not be able to identify what such compounds are, the contents of the specification and the knowledge of those skilled in the art speak to the contrary.

A skilled artisan would find the claimed genus of thiazolidinediones enabled by the specification because such an artisan would understand what a "thiazolidinedione" is. The thiazolidinedione moiety was well-known to skilled artisans at the time the present application was filed. *See, e.g.*, U.S. Patent 5,968,960, issued October 19, 1999, cited in the present specification at page 14, line 29 (use of thiazolidinediones for treatment of myocardial ischemia; see claim 2, for example). Further, each of the thiazolidinediones the Action has indicated as enabled comprises a thiazolidinedione moiety, as reflected in the systematic chemical names for these compounds: 5-[[4-[(3,4-dihydro-6-hydroxy-2,5,7,8-tetramethyl-2H-1-benzopyran-2-yl)methoxy]phenyl]methyl]-2,4-thioazolidinedione (troglitazone); 5-[[4-[2-(5-ethyl-2-pyridinyl)ethoxy]phenyl]methyl]thiazolidine-2,4-dione (pioglitazone); and 5-((4-(2-(methyl-2-pyridinylamino)ethoxy)phenyl)methyl)-2,4-thiazolidinedione (BRL49653). Moreover, numerous compounds in the patent documents incorporated by reference in the specification, as discussed above, comprise this moiety. Thus, contrary to the Action's assertions, the specification provides an identifiable, structural feature that is common to thiazolidinediones. As such, a skilled artisan would be able to ascertain the claimed thiazolidinediones of the present invention without undue experimentation.

### **3. The Specification Is Enabling For the Use of the Claimed Genus of Thiazolidinediones**

As a final note, the specification provides a skilled artisan with guidance regarding how to use the claimed thiazolidinediones within the scope of the present invention. MPEP § 2164

("The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention.")

Examples 1 and 2 of the specification, beginning at page 28, line 6, provide instructions as to how to perform an assay to measure the binding of a thiazolidinedione to the oxytocin receptor. Other assay information concerning thiazolidinediones and the oxytocin receptor that is commensurate in scope with the present claims is discussed at page 16 line 10, through page 17, line 3 of the specification. As has been determined by the courts, the scope of the enablement must only bear a "reasonable correlation" to the scope of the claims. *In re Fisher*, 427 F.2d at 839. Even when experiments are necessary, a considerable amount of routine experimentation is permissible, especially where the specification provides a reasonable amount of guidance with respect to the direction in which experimentation should proceed. *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986); *In re Wands*, 858 F.2d at 737 (citing *In re Angstadt*, 537 F.2d 489, 502-04 (CCPA 1976)). The guidance provided in the present specification reasonably allows a skilled artisan to practice the claimed invention without undue experimentation.

#### **4. Summary**

As discussed above, the present claims are enabled for at least the following reasons: the Action concedes that at least three specific examples of thiazolidinediones are enabled (and that is all that is needed to support enablement); the thiazolidinedione moiety is well-known and identifiable to those of skill in the art; and the specification provides numerous examples of thiazolidinediones that may be employed in methods of the present invention, including methods of obtaining, making and using them.

As the specification is enabling under 35 U.S.C. § 112, first paragraph, Applicant respectfully requests that the enablement rejection be withdrawn.

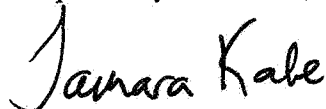
**C. The Indefiniteness Rejection Is Overcome**

Claim 9 is rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Specifically, the Action asserts that the phrase "a compound related to troglitazone" is unclear. Applicant disagrees, as one of ordinary skill in the art would understand what a compound related to troglitazone is. However, in an effort to advance prosecution in this case, this phrase has been removed from the claims. Applicant therefore respectfully requests that the indefiniteness rejection be withdrawn.

**D. Conclusion**

In view of the foregoing, it is respectfully submitted that each of the pending claims is in condition for allowance, and a Notice of Allowance is earnestly solicited. The Examiner is invited to contact the undersigned attorney at (512) 536-3015 with any questions, comments, or suggestions relating to the referenced patent application.

Respectfully submitted,



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